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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,958	01/03/2006	Jorg Sturzebecher	50125/102001	4120

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
01/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,958	STURZEBECHER ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-91* is/are pending in the application.

4a) Of the above claim(s) *49-69,71-73,75-89 and 91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48,70,74 and 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12 pages 04/08/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's request for continued examination filed on December 9, 2009.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Status of Claims

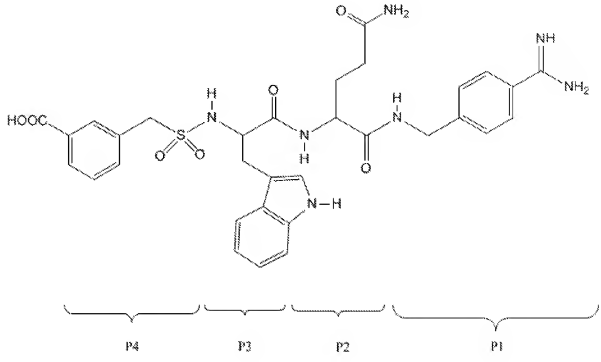
Amendment of claims 46, 48, 53 and 63 is acknowledged.

Claims 46-91 are currently pending and are the subject of this office action.

Claims 75, 77-81, and 82-87 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election has been treated as an election without traverse in the reply filed on August 18, 2008.

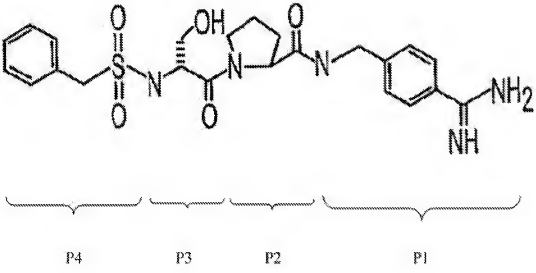
In the Office Action mailed on June 11 2009, the following species was under examination: N-[[3-carboxyphenyl)methyl]sulfonyl]-D-tryptophyl-N1-[[4-(aminoiminomethyl)phenyl]methyl]-L-Glutamamide (CAS# 446845-73-4 for the neutral

compound and 446845-74-5 for the trifluoroacetate salt), which corresponds to the following structure:



Due to Applicant's amendment of claim 46, the above species longer reads on any of the pending claims.

As a consequence the examination was expanded to the following species:



which reads on the following claims: 46-48, 70, 74 and 90.

Claims 46-48, 70, 74 and 90 are under examination.

Priority

The present application is a 371 of PCT/EP04/00247 filed on 01/15/2004.

Applicant claims priority to foreign application: GERMANY 103 01 300.8 filed on 01/15/2003. However, should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application. As a consequence, the priority date for this application is considered: 01/15/2004.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-47, 70, 74 and 90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 46-47, 70, 74 and 90 recite a large genus of compounds encompassed by the following structure: P4-P3-P2-P1 (I), wherein each P4, P3, P2 and P1 are optionally independently further monosubstituted, polysubstituted or unsubstituted.

M.P.E.P. #2163 states: "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention....one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process".

A description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the members of the genus, which features constitute substantial portion of the genus. See *Univ. of California vs. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112 first, by showing enablement of a representative number of species within the genus. A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.

Applicant has failed to show that he was in possession of all the diverse compounds encompassed by de general structure (I). Applicant discloses the specific structures of a very narrow set of compounds (see specification) with very few substituents , if any, in the P1, P2, P3 and P4 groups, despite claiming that the groups can be substituted without specifying or limiting the type of substitution.

This small set of compounds can not be viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Given the broad scope of the claimed subject matter, Applicant has not provided sufficient written description that would allow the skilled in the art to recognize all the compounds of claims 46-47, 70, 74 and 90 claimed.

In order to bring the claims in compliance with what is disclosed, it is suggested that applicant provides a more specific and narrower definition of the substituents for the groups P1, P2, P3 and P4.

Claim Rejections - 35 USC § 102

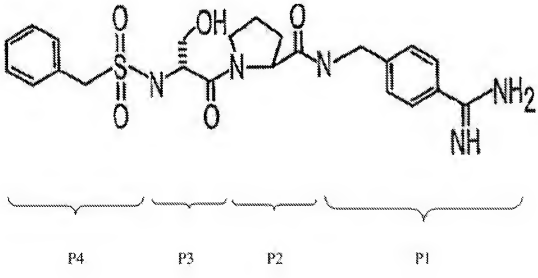
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-48, 70 and 74-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et. al. (WO 2002/014349).

For claims 46-48, Levy teaches: a method of treating a condition which is ameliorated by inhibiting or decreasing urokinase activity in a mammal in need of

treatment comprising the administration of compounds of claim 1 (see claim 1 and for example claim 71). More specifically Levy teaches compound J (see Figure 10F) which has the following structure:



which anticipates the structures of claims 46-48. Although the stereochemistry of the proline amino acid indicates a mixture of D and L stereoisomers, still this mixture anticipates the claims, since the claims recite the word "comprising" which does not exclude other ingredients, like in this case the D isomer.

Levy is silent regarding "inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa". However the recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for

completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Alternatively, even if one were to give some weight to the preamble, the claimed limitation *"inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa"* will inevitably flow from the teachings of Levy, since the same compound (Compound J above) is being administered to subjects (human patients in need of a decrease in urokinase activity) all of which have "plasma kallikrein and/or factor XIa and/or factor XIIa" in their cells, since as evidenced by Applicant's own admission these factors are present in any adult human (see specification pages 1-4). In other words, even though the prior art is silent regarding *"inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa"*, by practicing the method of Levy: "*a method of treating a condition which is ameliorated by inhibiting or decreasing urokinase activity in a mammal in need of treatment comprising the administration of compound J*", one will also be "*inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa with a composition comprising compound J*". MPEP 2112 I states: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

Claim 70 further limits claim 46, wherein the method of claim 46 is "for preventing blood coagulation at synthetic surfaces."

Although Levy does not explicitly teach that the method can be used for preventing blood coagulation at synthetic surfaces, the claimed limitation does not appear to result in a manipulative difference between the prior art method, since the claimed limitation appears to suggest an intended use of the claimed method and does not appear to further limit the patient population or provide any additional steps.

Claim 74 further limits claim 46, wherein compound A is administered in parenteral or enteral form. Claim 90 further limits claim 74, wherein parenteral form is intraarterial, intravenous, intramuscular or subcutaneous form.

For claims 74 and 90, Levy further teaches that the compounds can be administered can be parenteral such as intravenous injection (see page 60, lines 23-25).

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 102 (b)

Due to Applicant's amendment of claim 46, the 102(b) rejection based on Shiraishi et. al. is now moot.

Rejection under 35 USC 102(b) is withdrawn.

However, based on new prior art a new 102(b) rejection was applied (see above).

Claims rejected under 35 USC 103 (a)

Due to Applicant's amendment of claim 46, the 103(a) rejection based on Shiraishi et. al. is now moot.

Rejection under 35 USC 103 (a) is withdrawn.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1628.
December 2, 2010